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PPLICATION NO.	FILING DATE		FIRST NA	MED INVENTO	R	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,622	01/24/2000		Stu	art Edwards	<u> </u>	STUA0010	7398
. 75	90 10/07/20	003			,.	EXAM	IINER .
GLENN PATE					3	THISSELI	., JEREMY
3475 EDISON V SUITE L	WAY				,	ART UNIT	PAPER NUMBER
MENLO PARK	, CA 94025					3763	4

Please find below and/or attached an Office communication concerning this application or proceeding.

•	•	Application No.	Applicant(s)						
Office Action Summary		09/490,622	EDWARDS, STUART						
;	omoc Action Cummary	Examiner	Art Unit						
	The MAILING DATE of this communication app	Jeremy T. Thissell	3763						
Period fo	or Reply	ours on the cover sheet with the c	orrespondence address						
THE I - Exte after - If the - If NO - Failu - Any I	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION.  nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication.  period for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	66(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE.	nely filed s will be considered timely. the mailing date of this communication. D. (35.U.S.C. 8.133)						
1)⊠	Responsive to communication(s) filed on 24 J	<u>uly 2003</u> .							
2a)⊠	This action is <b>FINAL</b> . 2b)☐ Thi	action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.									
	ion of Claims	,							
	4) Claim(s) 1-38 is/are pending in the application.								
	4a) Of the above claim(s) 4.5,7,9-13,15-17,21,22 and 38 is/are withdrawn from consideration.								
_	· · · <del></del>								
	Claim(s) <u>1-3, 6, 8, 14, 18-20, 23-37</u> is/are rejected.								
	Claim(s) is/are objected to.								
	Claim(s) are subject to restriction and/or ion Papers	election requirement.							
	The specification is objected to by the Examiner								
	The drawing(s) filed on is/are: a) accep		niner						
, , ,	Applicant may not request that any objection to the								
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.									
If approved, corrected drawings are required in reply to this Office action.									
12) The oath or declaration is objected to by the Examiner.									
Priority u	ınder 35 U.S.C. §§ 119 and 120								
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a)[	☐ All b)☐ Some * c)☐ None of:								
	1. Certified copies of the priority documents	have been received.							
	2. Certified copies of the priority documents	have been received in Application	on No						
* 0	3. Copies of the certified copies of the priori application from the International Bur	eau (PCT Rule 17.2(a)).							
	See the attached detailed Office action for a list of the standard of a claim for demostic								
	cknowledgment is made of a claim for domestic ) $\square$ The translation of the foreign language prov								
	Acknowledgment is made of a claim for domestic								
Attachment	•	_							
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) Patent Application (PTO-152)						
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Art Unit: 3763

### **DETAILED ACTION**

Page 2

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 8, 14, 18, 19, 25-32, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian et al (US 5,674,287) in view of Guglielmi (US 5,916,235).

Slepian teaches all the claimed subject matter including local heating of an infused saline that is delivered directly from the catheter or through a "leaky balloon," as well as temperature control feedback. Col. 9, lines 53-66; col. 10, line 46; col. 14, line 37. However, Slepian does not teach shrinking the lumen down to a selected dimension, more specifically the normal dimension. Guglielmi teaches the shrinkage of enlarged body lumens by using heat. (col. 4, lines 31-32). It would have been obvious to use the body lumen heating procedure in Slepian for shrinking an enlarged body lumen as well, such as taught in Guglielmi, since such a treatment is well-known in the art, as taught by Guglielmi. One of ordinary skill in the art would have found it further obvious that the selected dimension would be the normal dimension of the body lumen,

Application/Control Number: 09/490,622

Art Unit: 3763

since returning the body to its normal condition/functional capacity is the goal of most medical procedures.

Claims 1, 2, 8, 14, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al (US 5,938,660) in view of Guglielmi (US 5,916,235).

Swartz teaches all the claimed subject matter including heating a saline solution (col. 11, lines 44-54). However, Swartz does not teach shrinking the lumen down to a selected dimension, more specifically the normal dimension. It would have been obvious to combine Guglielmi with Swartz for the same reasons it would have been obvious to combine Guglielmi with Slepian as discussed above.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz in view of Guglielmi and further in view of Goffinet (WO 85/02779).

Swartz as modified by Guglielmi teaches all the claimed subject matter except for the tissue being cancerous, engorged, inflamed, or infected. Goffinet teaches ablation (like Swartz) of malignant (cancerous) tumors. (page 1, line 2). It would have been obvious to one of ordinary skill in the art that a tissue to be ablated by Swartz would include cancerous tissue as taught by Goffinet, since ablation of cancerous tissue is well-known in the art, as demonstrated by Goffinet.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Guglielmi and further in view of Gencheff et al (US 5,423,744).

Slepian as modified by Guglielmi teaches all the claimed subject matter except for promoting epithelial growth. Gencheff teaches introduction of a medicinal agent and energy such that it promotes endothelial cell growth. (col. 6, lines 1-3). Endothelial cells are a kind of epithelial cells. It would have been obvious to one of ordinary skill in the art that the promotion of endothelial cells, as in Gencheff, is an important part of treatment of body lumens, and that it would be obvious to make it a part of Slepian's treatment.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz in view of Guglielmi and further in view of Lesh (US 5,971,983).

Swartz as modified by Guglielmi teaches all the claimed subject matter except for pacing. Lesh teaches treatment of the heart using an ablation catheter and a pacing device. It would have been obvious to perform the heart tissue ablation of Swartz and include the pacing device of Lesh, particularly since Swartz is concerned with the muscle stimulating electrical impulses of the heart.

## Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Art Unit: 3763

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3763

### Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BRIAN L. CASLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

October 2, 2003